REMARKS/ARGUMENTS

The rejections presented in the Final Office Action dated September 10, 2008 (hereinafter Office Action) have been considered. Claims 1-62 remain pending in the application. Claims 8-62 have been withdrawn by the Examiner by way of a restriction requirement made final. Claims 1 and 2 have been amended. Withdrawn claims 8-62 have been canceled without prejudice or disclaimer. New claims 63-75 have been added. No new matter has been added. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

Claims 1, 2, 5, and 7 are rejected based on 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,003,975 to Hafelfinger et al. (hereinafter "Hafelfinger").

Applicant maintains its position that a case of *prima facie* anticipation of claims 1, 2, 5, and 7 has not been made out in view of Hafelfinger. However, Applicant has amended the claims in a *bone fide* effort to advance prosecution.

Claim 1 has been amended to recite an implantable cardiac device that includes an implantable housing, a first electrode provided at the housing, and a second electrode supported by the housing. Each of the first and second electrodes define extra-thoracic, subcutaneous electrodes of the device. Monitoring circuitry is coupled to the first and second electrodes. The first and second electrodes are configured for extra-thoracic, subcutaneous cardiac activity sensing when the device is operated in a monitoring mode. Energy delivery circuitry is coupled to the first and second electrodes and adapted to couple to an intrathoracic lead electrode. The lead electrode and at least one of the first and second electrodes are configured for cardiac activity sensing and energy delivery when the device is operated in an energy delivery mode.

A lead interface is provided at the housing and is configured to receive an intrathoracic cardiac lead comprising the intrathoracic lead electrode. A controller is coupled to the lead interface, monitoring circuitry, and energy delivery circuitry. The controller is configured to execute program instructions for transitioning operation of the device from the monitoring mode, in which the energy delivery circuitry is disabled and only extra-thoracic, subcutaneous electrodes including at least the first and second

electrodes are used for extra-thoracic, subcutaneous cardiac activity sensing, to the energy delivery mode, in which the energy delivery circuitry is enabled and the lead electrode and at least one of the first and second electrodes is configured for cardiac activity sensing and energy delivery, at least in part in response to coupling the intrathoracic cardiac lead to the lead interface.

Support for the amendments made to claim 1 can be found, for example, in the following excerpted portions of the specification, among others:

> Cardiac signals are sensed, for example, using the subcutaneous electrode(s) 314 and the can or indifferent electrode 307 provided on the cardiac device housing. Cardiac signals may also be sensed using only the subcutaneous electrodes 314, such as in a non-active can configuration. Cardiac signals may also be sensed using only sensors and/or electrodes in or on the can when the control system 305 is operating in the first (monitoring and recording) mode.
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> Page 18, lines 15-20 and Figure 4.

> The system 200 shown in Figure 3 is suitable for implanting in a patient and used for recording cardiac related signals in a first operating mode. In the first operating mode, the system 200 may include only sensors in or on a housing 103 or the system 200 may include one or more other sensors and/or electrodes as will be further described below. When the system 200 is configured to operate in a second monitoring and therapy mode, typically cardiac electrodes are attached to the housing 103, such as, for example, using the header 100.
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> Page 13, lines 17–23.

> A reconfigurable cardiac device in accordance with the present invention includes a therapy portion 300, which is disabled when the cardiac device is operated in a first monitoring and recording mode, and enabled when operating in a second monitoring and therapy mode. The therapy portion 300 may be physically switchable, using a hardware switch, to enable/disable the therapy portion 300. The therapy portion may be enabled/disabled via control signals from the control system 305. It is also contemplated that a combination of hardware and software may be used to enable/disable the therapy portion 300. For example, the header 100 (see for example, Figures 7 and 8) may include a proximity switch or other component required to enable

the therapy portion 300. The control system 305 may require detection of one or more therapy electrodes before enabling the therapy portion 300.

Page 20, lines 17-24.

A reconfigurable cardiac monitoring/stimulation device may advantageously be used where it is desired to provide cardiac monitoring for diagnosis, before providing cardiac stimulation therapy. For example, a reconfigurable approach of the present invention allows upgrading the device from purely a monitoring and diagnostic system to a therapy delivery system for patients who develop or are diagnosed with conditions necessitating cardiac therapy.

Page 9, lines 7-13.

The object of the Hafelfinger device is to use the load impedance presented by the lead/tissue interface during a stimulation pulse to determine the integrity of the implanted leads and to automatically change the electrode configuration to an available and operative configuration. If the measured lead impedance does not fall within a prescribed range, the pacemaker will automatically change the electrode configuration between tip-to-ring, tip-to-case, and ring-to-case in a prescribed sequence. Once the new configuration is determined, the pacemaker's programmed configuration is changed to the new configuration, the physician is alerted upon the next interrogation of the change, and pacing and sensing functions continue using the new configuration. Column 4, lines 10-18.

Hafelfinger does not teach, suggest or contemplate several features of Applicant's claim 1. For example, Hafelfinger does not disclose or suggest a first electrode provided at the housing and a second electrode supported by the housing, wherein each of the first and second electrodes define extra-thoracic, subcutaneous electrodes of the device. Hafelfinger does not teach or suggest a controller configured to execute program instructions for transitioning operation of the device from a monitoring mode, in which energy delivery circuitry is disabled and only extra-thoracic, subcutaneous electrodes including at least the first and second electrodes are used for extra-thoracic, subcutaneous cardiac activity sensing, to an energy delivery mode, in which the energy delivery circuitry is enabled and the lead electrode and at least one of the first and second electrodes is configured for cardiac

activity sensing and energy delivery, at least in part in response to coupling an intrathoracic cardiac lead to a lead interface of the housing.

Applicant traverses the anticipation rejection of claims 1, 2, 5, and 7 because Hafelfinger does not show "the identical invention . . . in as complete detail as is contained in the ... claim" MPEP §2131 (citing *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1239, 9 U.S.P.Q.2d 1913, 1920 (Fed Cir. 1989). The Federal Circuit recently held that "[b]ecause the hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements 'arranged as in the claim.'" (*Net Moneyin, Inc. v. Verisign, Inc.*, --- F.3d ----, 2008 WL 4614511 (Fed. Cir. 2008) quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)).

Because Hafelfinger does not teach all elements of Applicant's claims 1, 2, 5, and 7, these claims are not anticipated by Hafelfinger. Applicant respectfully requests withdrawal of the anticipation rejection of claims 1, 2, 5, and 7.

Claims 3 and 6 are rejected based on 35 U.S.C. §103(a) as being unpatentable over Hafelfinger in view of U.S. Patent No. 5,318,593 to Duggan (hereinafter "Duggan"). Claim 4 is rejected based on 35 U.S.C. §103(a) as being unpatentable over Hafelfinger in view of U.S. Patent No. 6,205,357 to Ideker et al. (hereinafter "Ideker").

The obviousness rejections of claims 3, 4, and 6 are based largely on the primary reference Hafelfinger. As discussed above, Hafelfinger fails to teach several features of Applicant's claim 1 from which claims 3, 4, and 6 depend. Duggan and Ideker do not supply the elements of Applicant's claims 1, 3, 4, and 6 that are clearly missing from Hafelfinger.

Because the asserted combination of references fails to teach or suggest several of the above-identified limitations, Applicant respectfully asserts that the Examiner has not established *prima facie* obviousness of Applicant's subject matter recited in claims 3, 4, and 6. MPEP § 2142. Applicant respectfully requests withdrawal of the obviousness rejections of claims 3, 4, and 6.

New claims 63-75 depend from claim 1 and are directed to allowable for reasons discussed above. Support for these claims can be found in the reproduced excerpts of the specification provided above and elsewhere. No new matter has been added.

For at least the reasons presented above, and those presented in the prior responsive communications, Applicant respectfully submits that the present rejections of claims 1-7 are unsupportable. Applicant respectfully requests withdrawal of the rejections and solicits an indication that the pending and new claims are in condition for allowance.

Authorization is given to charge Deposit Account No. 50-3581 (GUID.048US01) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the Examiner is invited to contact the undersigned attorney to discuss any issues related to this case.

Respectfully submitted,
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Date: December 10, 2008

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